

**Appl. No.** : **10/735,481**  
**Filed** : **December 12, 2003**

**AMENDMENTS TO THE DRAWINGS**

Figures 2-5 have been amended: legends for each bar have been added.

**Appl. No.** : 10/735,481  
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### **REMARKS**

Claims 6, 31, 33, 35, 41 and 47 are withdrawn. Claims 2, 37, 43, and 47 are under consideration. Applicant understands that upon allowance of the peptide claims, the method claims 31-35 may be considered for rejoinder. Claims 2 and 48 have been amended to correct a typographical error. New Claims 49-51 have been added. Support for the new claims can be found in the Specification as filed, for example, on page 12 in Example 4, wherein synthetically prepared peptide of SEQ ID NOs 2 and 3 were prepared and tested for antimicrobial effects. No new matter has been introduced by these amendments. The following addresses the substance of the Office Action.

#### **Drawings**

The Examiner has objected to drawings of Figures 2-5 for not accurately indicating what each bar represents. Applicant is now submitting drawings amended accordingly. Support for the amendment in the figures can be found in the Specification as filed in paragraphs [0080]-[0083]. The Examiner further requested that a header "Brief Description of Figures" be inserted into the Specification prior to the description of the figures. Applicant directs the Examiner's attention to page 7 of the Specification as filed, wherein such header has been present between paragraphs [0042] and [0043].

#### **Claim Objections**

The Examiner has objected to Claims 2 and 48 for misspelling "dermicidin", wherein it should have been spelled as "dermcidin". Applicant has amended these claims accordingly.

#### **Novelty**

The Examiner has maintained the rejection of Claims 2, 4, 37, 39, 43 and 45 under 35 USC §102(b) as being allegedly anticipated by Akerblom et al. (USP 5,834,192).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Akerblom et al. describe an HCAP protein, 110 aa long, suggested to be involved in cancer-induced cachexia. Akerblom et al. does not disclose an isolated antimicrobially active peptide comprising amino acid residues 63-110 (SEQ ID NO: 2) of a dermcidin (DCD) protein

Appl. No. : 10/735,481  
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substantially in isolation from sequences naturally occurring adjacent thereto in the dermcidin protein. The Examiner's attention is drawn to this negative limitation in Claims 2 and 48. The rule according to MPEP 2173.05(i) is:

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph.

A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. In re Wakefield, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. In re Barr, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

In this application, the inventors synthesized two peptide fragments, which, by definition, are in isolation from sequences naturally occurring adjacent thereto in the dermcidin protein. The peptides, including the one of SEQ ID NO: 2, were experimentally shown to have antimicrobial effects. Akerblom et al. do not teach such peptides. Akerblom et al. also do not teach antimicrobially active peptide consisting essentially of a fragment of the C-terminal of dermcidin protein, said fragment comprising a maximum of 50 amino acids of said C-terminal. Instead, Akerblom teaches a full-length 110 aa or a mature 90 aa long protein that was found to be associated with cachexia. The Examiner further stated that there is nothing on the record via a side-by-side comparison to show that the peptide of the prior art would not have the same activity of the instantly claimed peptide, and that because amino acid residues 63-110 are present in the protein of Akerblom, such protein would inherently have antimicrobial activity. The issue here is not if the full length 110 aa or mature 90 aa protein of Akerblom would inherently be antimicrobial, but that Akerblom does not teach the claimed peptides.

Therefore, Akerblom et al. does not anticipate Claims 2, 37, 43 and 48, and the rejection of these claims under 35 USC §102(b) should be withdrawn.

#### **Written description**

The Examiner has rejected Claim 2 under 35 USC §112, first paragraph as allegedly containing new matter. Specifically, the Examiner requested that the Applicant specifically points out the support for the limitation "substantially in isolation from sequences naturally occurring adjacent thereto in the dermcidin protein". As the Applicant had shown in the

**Appl. No.** : **10/735,481**  
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previously filed amendment, support for this limitation can be found in the Specification as filed, on page 12 in Example 4. The inventors synthesized the peptide of SEQ ID NOs 2 and tested it for antimicrobial effects. The synthesized fragment of a larger protein is, by definition, substantially in isolation from sequences naturally occurring adjacent thereto in the larger protein. Therefore, Claim 2 is fully supported by the Specification as filed, and its rejection under 25 USC §112, second paragraph should be withdrawn.

### **CONCLUSION**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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